**REMARKS**

Claims 1-9 and 12-24 are currently pending. No claims have been amended herein. Applicants respectfully request reconsideration and allowance of all pending claims.

**1. Rejection of the Claims under 35 U.S.C. §112, first paragraph**

Reconsideration is requested of the rejection of claim 24 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The Office has stated that the claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. In particular, the Office alleges that the specification supports only evaluating lean body mass and fat body mass in preterm infants, but that there is no support for evaluating an "infant," which is a broader embodiment of the described preterm infants.

Applicants respectfully disagree, as the instant specification sufficiently describes evaluating the lean body mass and fat body mass of an infant after feeding the infant a nutritional formula comprising a source of DHA and ARA such that one skilled in the art could reasonably conclude that the inventors had possession of the claimed invention.

M.P.E.P. 2163 states that the first paragraph of 35 U.S.C. 112 requires that the "specification shall contain a written

description of the invention…To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention." Furthermore, subject matter that is conventional or well known to one of ordinary skill in the art need not be disclosed in detail. Specifically, if a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate description requirement is met.[1]

In the present case, support for the step of evaluating the lean body mass and fat body mass of an infant can be found in the specification on page 15, which describes measuring the total body fat and total lean mass of infants.[2] Although the description on page 15 of measuring total body fat and total lean mass of infants was taken from the Example, which evaluates the body composition of premature infants fed formula comprising DHA and ARA, applicants note that the specification of the instant application clearly describes applying the disclosed methods to infants in general, including both preterm and term infants. For example, page 9, line 29 of the specification states: "The method of the present invention may be applied to both term and preterm infants." The specification thus describes evaluating the lean body mass and fat body mass of an

[1] *See, e.g., Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384 (Fed. Cir. 1986); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991); *Martin v. Johnson*, 454 F.2d 746, 751, 172 USPQ 391, 395 (CCPA 1972).

[2] *See also* Specification at p. 11, lines 20-21.

infant, and indicates that the methods disclosed therein may be applied to both term and preterm infants.

Based on the foregoing, applicants submit that the limitation of claim 24 relating to evaluating the lean body mass and fat body mass of an infant is adequately described by the instant specification and accordingly, this rejection should be withdrawn.

**2. Rejection of the Claims under 35 U.S.C. §102(b)**

Reconsideration is requested of the rejection of claims 1-9[3] and 12-23 under 35 U.S.C. §102(b) as being anticipated by O'Connor, et al. (U.S. Application Publication No. 2002/0045660).

Claim 1 is directed to a method of increasing lean body mass and reducing fat body mass in preterm infants. The method comprises feeding the preterm infant a nutritional formula comprising DHA and ARA from fish and fungal oil for the purpose of increasing lean body mass and reducing fat body mass in the preterm infant. The lean body mass of the preterm infant is increased by at least about 4% at 12 months corrected age as compared to preterm infants fed a control nutritional formula that does not comprise a source of DHA and ARA.

O'Connor, et al. is directed to "[m]ethods for providing nutrition and for enhancing neurological development of preterm infants," and to "an improved nutritional composition containing

specified amounts of [docosahexaenoic acid (DHA)] and [arachidonic acid (ARA)] as well as their precursor essential fatty acids alpha-linolenic and linoleic acids."[4] The method comprises feeding infants nutrient-enriched formulas supplemented with long chain polyunsaturated fatty acid, including both DHA and ARA, for an extended feeding regimen, typically at least three months corrected age, and preferably to 6 or 12 months corrected age.[5] O'Connor, et al. state that the methods described therein do not result in growth inhibition of the infants, such as that previously observed when DHA without ARA was used, and also result in improved or enhanced neurological development, such as visual, motor, and language development.[6]

Significantly, O'Connor, et al. fail to disclose or suggest feeding a nutritional formula comprising DHA and ARA to a preterm infant for the purpose of increasing lean body mass and reducing fat body mass in the infant, as required by claim 1. As noted above, O'Connor, et al. state that the ARA and DHA supplemented formulas described therein may improve or enhance neurological development, such as visual, motor, and language development, but do not disclose or suggest that such formulas have any effect on body composition, such as increasing lean body mass and reducing fat body mass.

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[3] In the current action, the Office has rejected claim 10 under §102(b) as being anticipated by O'Connor, et al. Applicants assume this is a typographical error, as claim 10 was cancelled in a previous amendment.
[4] O'Connor, et al. at abstract.
[5] *Id.*
[6] *Id.* at paragraphs 64 and 66.

In the current action, the Office has once again taken the position that even though O'Connor, et al. do not literally disclose that a formula comprising DHA and ARA will increase lean muscle mass and reduce fat body mass in preterm infants, claiming a new use, new function, or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. Applicants respectfully submit that O'Connor, et al. do not inherently anticipate claim 1.

"Under principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claims limitations, it anticipates."[7] However, new uses of known processes may be patentable;[8] that is, principles of inherency do not prohibit a process patent for a new use of an old structure. For instance, the Federal Circuit in *Perricone v. Medicis Pharm. Corp.* held that a method claim for treating skin sunburn comprising "topically applying [a composition] to the *skin sunburn*" was not inherently anticipated by a prior art teaching of a method for topically applying the composition to skin. The court reasoned that as the prior art reference did not disclose topical application to skin sunburn, the prior art did not teach the method of the claim at issue.[9] The court did, however, hold that a method claim "for preventing sunburn damage to exposed skin surfaces, comprising topically applying [the composition] to said skin surfaces" was anticipated by the same prior art. The court reasoned that this claim merely required application

[7] *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1376 (Fed. Cir. 2005).
[8] *See Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F3d. 1368, 1376 (Fed. Cir. 2001).
[9] *Perricone v. Medicis Pharm. Corp.* at 1379.

of the composition to exposed skin surfaces, and because all skin surfaces are susceptible to sunburn damage and one can only realistically apply a composition to a skin surface when that surface is exposed, the "topical application" disclosed in the prior art encompassed the claimed method.[10]

In the instant case, there is no disclosure in O'Connor, et al. of administering a nutritional formula comprising DHA and ARA to a preterm infant for the purpose of increasing lean body mass and reducing fat body mass in the infant. Nor has the Office pointed to anything in O'Connor, et al. to suggest that the methods of O'Connor, et al. inherently require feeding the formulas disclosed therein to a preterm infant for the purpose of increasing lean body mass and reducing fat body mass in the infant. At best, O'Connor, et al. disclose administering the ARA and DHA supplemented formulas described therein for the purpose of improving or enhancing neurological development, such as visual, motor, and language development, in an infant, but say nothing about their formulas having any effect on body composition, such as lean body mass and fat body mass, in the infant.

In contrast, applicants' claim 1 requires feeding a preterm infant the claimed formulas for the purpose of increasing lean body mass and reducing fat body mass in the infant. It may not always be desirable in every instance to decrease fat body mass in all preterm infants. Such a distinction would not be apparent from the teachings of the O'Connor, et al. reference,

[10] *Id.*

which, as noted above, disclose administering the ARA and DHA supplemented formulas described therein for the purpose of improving or enhancing neurological development, but mention nothing about increasing lean body mass and reducing fat body mass in preterm infants.

Thus, just as the unanticipated method in *Perricone* required application to a subset of the generally described skin of the prior art, the method set forth in claim 1 requires administration to a subset of the generally described preterm infant population disclosed in O'Connor, et al.; i.e., preterm infants in which it would be desirable to increase lean body mass and reduce fat body mass. Accordingly, as O'Connor, et al. fail to teach administration of a nutritional formula comprising DHA and ARA to a preterm infant in which it would be desirable to increase lean body mass and reduce fat body mass, for the purpose of increasing lean body mass and reducing fat body mass in the preterm infant, O'Connor, et al. fail to teach each and every limitation of applicants' claim 1.

As stated in MPEP §2131, a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. Since O'Connor, et al. fail to disclose feeding a preterm infant a nutritional formula comprising DHA and ARA from fish and fungal oil for the purpose of increasing lean body mass and reducing fat body mass in the infant, and generally fail to disclose or suggest that the formulas disclosed therein have any affect on body mass, O'Connor, et al. fail to disclose each and

every limitation of claim 1. As such, claim 1 is novel over the cited reference.[11]

Claims 2-9, 12-16, and 19 depend from claim 1 and are thus patentable over O'Connor, et al. for the same reasons as set forth above for claim 1, as well as for the additional elements they require.

Additionally, claim 16 depends from claim 1 and further comprises evaluating the lean body mass and fat body mass of the preterm infant after feeding the preterm infant the nutritional formula. The Office has stated that evaluating infant growth is done periodically as a routine and was done and disclosed by O'Connor, et al. The Office has also stated that the neurological developments disclosed in O'Connor, et al. include motor development, and suggests that the lean body mass is mainly muscles and the motor development depends on muscle mass. Applicants respectfully disagree with the Office's

[11] Applicants would also like to address a point made by the Office in the Response to Arguments section of the current action. Specifically, the Office indicates that the recitation in claim 1 of "increasing lean body mass and reducing fat body mass" is included in the preamble, and the preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness. In response, applicants note that a limitation relating to increasing lean body mass and reducing fat body mass is, in fact, included in the body of claim 1, not just in the preamble. Specifically, claim 1 recites that the method comprises "feeding the preterm infant a nutritional formula comprising DHA and ARA from fish and fungal oil for the purpose of increasing lean body mass and reducing fat body mass in the preterm infant…" As noted above, this limitation implies that the preterm infant to whom the formula is fed is one for which it is desirable to achieve an increase in lean body mass and a reduction in fat body mass. The requirement that the nutritional formula comprising DHA and ARA be administered to a preterm infant for the purpose of increasing lean body mass and reducing fat body mass in the infant is thus a limitation in claim 1 that cannot be ignored.

interpretation of O'Connor, et al., and submit that this statement is not evidence that O'Connor, et al. inherently disclose applicants' claimed method.

Specifically, as noted above, the O'Connor, et al. method comprises feeding infants nutrient-enriched formulas supplemented with long chain polyunsaturated fatty acid, including both DHA and ARA, for an extended feeding regimen. O'Connor, et al. state that the methods described therein do not result in growth inhibition of the infants, such as that previously observed when DHA without ARA was used, and also result in improved or enhanced neurological development, such as visual, motor, and language development. Applicants note, however, that the terms "growth" and "motor development," as used in O'Connor, et al., do not mean increasing lean body mass and reducing fat body mass.

For example, paragraph 109 of O'Connor, et al. clearly defines "growth" as "anthropometric growth," which generally refers to "the increase in physical size of the infant and is measured by physical metrics such as weight, length and head circumference." Nowhere do O'Connor, et al. indicate that "growth" has anything to do with increasing lean muscle mass and reducing fat body mass.

Likewise, paragraph 112 of O'Connor, et al. defines "motor development" as referring to "an infant's ability to control and coordinate its muscles to make desired movements—another measure of neurological development." O'Connor, et al. thus clearly indicate that "motor development" is a type of neurological

development. Nowhere do O'Connor, et al. indicate that "motor development" has anything to do with increasing lean muscle mass and reducing fat body mass. Applicants further note that all infants have muscles, and presumably would be capable of showing an improvement in "motor development" if subjected to the O'Connor, et al. method. The Office, however, has failed to provide any evidence that an improvement in motor development is in any way tied to an increase in lean muscle mass and a reduction in fat body mass.

In the Response to Arguments section of the current action, the office indicates that these arguments are correct, and acknowledges that O'Connor, et al. limits motor development to neurological development only. In view of this admission and the above discussion, applicants submit that the disclosure of "growth" measurements in O'Connor, et al. is not a disclosure of evaluating the lean body mass and fat body mass of an infant fed a nutritional formula comprising DHA and ARA. Claim 16 is thus patentable over O'Connor, et al. for this additional reason.

Claim 17 is directed to a method of increasing lean body mass and reducing fat body mass in preterm infants. The method comprises feeding the preterm infant a nutritional formula comprising DHA and ARA from fish and fungal oil; and evaluating the lean body mass and fat body mass of the preterm infant after feeding the preterm infant the nutritional formula. The lean body mass of the preterm infant is increased by at least about 4% at 12 months corrected age as compared to preterm infants fed a control nutritional formula that does not comprise a source of DHA and ARA. For the reasons set forth above for claim 16,

applicants submit that O'Connor, et al. fail to disclose or suggest evaluating the lean body mass and fat body mass of an infant after feeding the infant the formulas disclosed therein. Claim 17 is thus also patentable over O'Connor, et al.

Claim 18 depends from claim 17 and is thus patentable over the cited references for the same reasons as set forth above for claim 17, as well as for the additional elements it requires.

Independent claims 20 and 22-23 are patentable over O'Connor, et al. for the same reasons as set forth above for claim 1.

Claim 21 depends from claim 20 and thus is patentable over the cited reference for the same reasons as set forth above for claim 20, as well as for the additional elements it requires.

**3. Rejection of the Claims under 35 U.S.C. §103(a)**

Reconsideration is requested of the rejection of claims 1-9 and 12-24 under 35 U.S.C. §103(a) as being unpatentable over O'Connor, et al. (U.S. Patent Application No. 2002/0045660) in view of Raclot, et al. ("Site-specific regulation of gene expression by n-3 polyunsaturated fatty acids in rat white adipose tissues," J. of Lipid Research, 1997, Vol. 38, p. 1963-1972).

O'Connor, et al. is discussed above. Significantly, O'Connor, et al. fail to disclose or suggest feeding a preterm infant a nutritional formula comprising DHA and ARA for the

purpose of increasing lean body mass and reducing fat body mass in the infant. Raclot, et al. fail to overcome this deficiency.

Specifically, Raclot, et al. describe a study investigating whether fatty acid synthase (FAS), hormone-sensitive lipase (HSL), lipoprotein lipase (LPL), phosphoenolypyruvate carboxykinase (PEPCK), CCAAT/enhancer binding protein α (C/EBPα), and leptin mRNA levels are affected in retroperitoneal (RP) and subcutaneous adipose tissues (SC) of rats fed n-3 PUFAs. For four weeks, the rats were fed high fat diets (20% fat) containing n-3 PUFAs given as eicosapentaenoic acid (EPA group), DHA, a mixture of EPA and DHA (MIX group), or native fish oil, or a control group fed with lard plus olive oil. Raclot, et al. found the fatty acid compositions of RP and SC to be similar and to resemble that of dietary fat within each experimental group. In RP, the FAS, HSL, PEPCK, LPL, C/EBPα, and leptin mRNA levels decreased as compared to control. In contrast, n-3 PUFAs had no affect on gene expression in SC. Raclot, et al. concluded that n-3 PUFAs (mainly DHA) affect gene expression in a site-dependent manner in white adipose tissues via possible antiadipogenic effects.

Significantly, however, Raclot, et al. fail to disclose or suggest feeding a preterm infant a nutritional formula comprising DHA and ARA for the purpose of increasing lean body mass and reducing fat body mass in the infant, as required by claim 1. Nor do Raclot, et al. disclose or suggest that nutritional formulas comprising the combination of ARA and DHA increase lean body mass and reduce fat body mass generally. Rather, as noted above, Raclot, et al. generally describe the

effect of dietary n-3 PUFAs on adipose tissue gene expression in retroperitoneal and subcutaneous adipose tissues of rats. There is no disclosure in Raclot, et al. of how ARA, or more particularly the combination of ARA and DHA would affect adipose tissues of preterm infants, or more particularly lean muscle mass and fat body mass.

In order for the Office to show a *prima facie* case of obviousness, M.P.E.P. §2142 requires a clear articulation of the reasons why the claimed invention would have been obvious. Specifically, the Supreme Court in KSR International Co. v. Teleflex Inc., 550 U.S. 398, 82 USPQ2d 1385, 1396 (2007) noted that the burden lies initially with the Office to provide an explicit analysis supporting a rejection under 35 U.S.C. 103. "[R]ejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some **articulated reasoning** with some **rational underpinning** to support the legal conclusion of obviousness."[12] The Court in *KSR International* further identified a number of rationales to support a conclusion of obviousness which are consistent with the proper "functional approach" to the determination of obviousness as laid down in Graham v. John Deere Co. (383 U.S. 1, 148 USPQ 459 (1966). Specifically, as previously required by the TSM (teaching, suggestion, motivation) approach to obviousness, one exemplary rationale indicated requires some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed

invention.

Specifically, to reject a claim based on this rationale, the Office must articulate the following: (1) a finding that there was some teaching, suggestion, or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings to arrive at each and every limitation of the claimed invention; (2) a finding that there was reasonable expectation of success; and (3) whatever additional findings based on the *Graham* factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness. The Office has failed to meet its burden under number (1) above, as the cited references fail to show each and every limitation of Applicants' invention and there is no apparent reason for one skilled in the art to modify the references to arrive at each and every limitation. It simply would not have been obvious to one skilled in the art to arrive at Applicants' claimed combinations.

Initially, applicants note that none of the cited references disclose or suggest feeding a preterm infant a nutritional formula comprising DHA and ARA for the purpose of increasing lean body mass and reducing fat body mass in the infant, as required by claim 1. At best, O'Connor, et al. state that the ARA and DHA supplemented formulas described therein may improve or enhance neurological development, such as visual,

[12] *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006) (emphasis added).

motor, and language development, without findings of anthropometric growth faltering or inhibition. Nowhere, however, is there any suggestion that the formulas of O'Connor, et al. have any effect on body composition, such as increasing lean body mass and reducing fat body mass, or should be fed to a preterm infant for the specific purpose of increasing lean body mass and reducing fat body mass in the infant. The Raclot, et al. reference, while evaluating the effects of dietary n-3 PUFAs on gene expression in adipose tissue of rats, failed to suggest that the combination of DHA and ARA would increase lean muscle mass and reduce fat body mass in preterm infants. Thus, the requirement in applicants' claim 1 that a nutritional formula comprising DHA and ARA be fed to a preterm infant for the specific purpose of increasing lean body mass and reducing fat body mass in the infant is entirely lacking from the cited references.

Nor is there apparent reason for one skilled in the art to modify the cited references to arrive at applicants' claimed method. As recognized by the Supreme Court in KSR International Co. v. Teleflex, Inc, while an obviousness determination is not a rigid formula, the TSM (teaching, suggestion, motivation) test captures a helpful insight: "A patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. Although common sense directs [caution as to] a patent application that claims as innovation the combination of two known [elements] according to their established functions, it can be important to identify a reason that would have prompted a

person of ordinary skill in the [art] to combine the elements in the way the claimed new invention does."[13]

As discussed in the specification of the instant application, applicants' have discovered that infants fed a nutritional formula comprising DHA and ARA, or a suitable source thereof, can increase lean body mass and reduce fat body mass as compared to an unsupplemented control formula, without having an impact on the rate of overall growth of the infant.[14] In contrast, none of the cited references disclose or recognize that the combination of DHA and ARA has any effect on body mass, or more specifically can result in an increase lean body mass and a reduction in fat body mass in infants. Given this lack of disclosure and recognition, why would one skilled in the art modify the teachings of the cited reference to arrive at a method comprising feeding a preterm infant a nutritional formula comprising DHA and ARA for the specific purpose of increasing lean body mass and reducing fat body mass in the infant, as required in the method of Applicants' claim 1? There is simply no apparent reason to make this modification.

Accordingly, there is no articulated reason to combine or modify the teachings of the cited references to arrive at each and every limitation of Applicants' claim 1. As such, claim 1 cannot be said to be obvious in view of the cited references.

In the current action, the Office has stated that it would have been obvious to include ARA and DHA in a preterm infant

[13] 2007 WL at 5.
[14] *See* Specification at p. 2, lines 13-16, and 24-27.

formula to achieve an increase in the muscular tissue while limiting the increase in fat cell size as disclosed by the combination of O'Connor, et al. and Raclot, et al. Applicants respectfully disagree.

For the reasons set forth above, neither of the cited references, alone or in combination, suggest that the combination of ARA and DHA, when fed to a preterm infant, could increase the lean body mass and reduce the fat body mass of the infant. Although Raclot, et al. do state that dietary n-3 PUFAs limit abdominal fat deposit hypertrophy, Raclot, et al. says nothing about the effect the combination of DHA and ARA would have on abdominal fat deposit hypertrophy. As will be recognized by those skilled in the art, changing the combination of polyunsaturated fatty acids present in an infant formula can alter how the formula affects the infant, be it in changes in growth, neurological development, etc. In the instant case, there is nothing in either of the cited references to suggest that the specific combination of DHA and ARA would result in an increase in lean body mass and a reduction in fat body mass when administered to a preterm infant in a nutritional formula.

In the Response to Arguments section of the current action, the Office has indicated that applicants' arguments that Raclot, et al. fail to disclose or suggest that the combination of ARA and DHA would increase lean body mass and reduce fat body mass in preterm infants are not persuasive, because Raclot, et al. was relied upon for teaching that n-3 PUFAs limit abdominal fat depot hypertrophy, while O'Connor, et al. is the primary reference, and this reference discloses a method that inherently

would result in increasing lean body mass and decreasing fat body mass in preterm infants. Applicants submit, however, that for the reasons set forth above, the method disclosed in O'Connor, et al. is not the same as the method set forth in claim 1, and O'Connor, et al. provide no suggestion that the nutritional formulas disclosed therein should be administered to infants in which it would be desirable to increase lean body mass and reduce fat body mass.

As none of the cited references disclose or suggest that the combination of DHA and ARA has any effect whatsoever on lean body mass and fat body mass, much less suggest feeding a preterm infant a nutritional formula comprising DHA and ARA for the specific purpose of increasing lean body mass and reducing fat body mass in the infant, it would not be obvious to modify the methods disclosed in O'Connor, et al. so that the nutritional formulas disclosed therein are fed to preterm infants in which it is desirable to increase lean body mass and reduce fat body mass. Claim 1 is thus patentable over the cited references.

As claims 2-9, 12-16, and 19 depend directly or indirectly from claim 1, claims 2-9, 12-16, and 19 are patentable for the same reasons as claim 1, as well as for the additional elements they require.

Furthermore, with regard to claims 16-17, applicants note that none of the cited references disclose evaluating the lean body mass and fat body mass of an infant after feeding the infant a nutritional formula comprising DHA and ARA.

In the Response to Arguments section of the current action the Office has, however, taken the position that the motivation for evaluating body mass index is well known in the art, as evidenced by Wells ("A Hattori chart analysis of body mass index in infants and children," International Journal of Obesity, 2000, Vol. 24, p. 325-329). Wells evaluated the effects of variation in fat free mass and fat mass on body mass index (BMI) in infants and children. Wells concludes that BMI is of limited use as a measure of body fatness in individuals in infancy and childhood, and that the continued emphasis on BMI for routine assessment of body fat in individuals risks failing to identify both excess fatness and its risk factors in the pediatric population.[15]

Applicants note, however, that while Wells describes evaluating the effectiveness of using BMI as a measure of fat free mass and fat mass in infants and children, there is nothing in Wells to suggest that feeding infants a nutritional formula comprising DHA and ARA has any effect on lean body mass or fat body mass in the infant, or that it would be desirable to evaluate the lean body mass and fat body mass of an infant fed such a nutritional formula following feeding. Wells thus fails to overcome the above-discussed deficiencies of O'Connor, et al. and Raclot, et al.; i.e., none of the cited references disclose or suggest evaluating the lean body mass and fat body mass of an infant after feeding the infant a nutritional formula comprising DHA and ARA. Claims 16-17 are thus also patentable over the cited references.

[15] Wells at p. 328, last paragraph.

Claim 18 depends from claim 17 and is thus patentable over the cited references for the same reasons as set forth above for claim 17, as well as for the additional elements it requires.

Independent claims 20 and 22-23 are patentable over the cited references for the same reasons as set forth above for claim 1.

Claim 21 depends from claim 20 and thus is patentable over the cited references for the same reasons as set forth above for claim 20, as well as for the additional elements it requires.

Claim 24 is patentable over the cited references for the same reasons as set forth above for claim 17.

**CONCLUSION**

In light of the foregoing, applicants request withdrawal of the rejections of claims 1-9 and 12-24 and allowance of all pending claims. The Commissioner is hereby authorized to charge the fee for the filing of an RCE as well as any additional government fees which may be required to Deposit Account No. 01-0025.

Respectfully Submitted,

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